IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

GENENTECH, INC., CITY OF HOPE, and HOFFMANN-LA ROCHE INC.,	)	
Plaintiffs,	)	Redacted: Public Version
v.	)	C.A. No. 18-095-GMS
CELLTRION, INC., CELLTRION HEALTHCARE, CO. LTD., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICALS INTERNATIONAL GMBH,	)	[redacted]
Defendants.	)	

DEFENDANTS' OPENING BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS OR STAY

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INTRODUCTION

This is the second lawsuit filed involving the same parties, the same patents, and the same pharmaceutical product. Because it is the *second* such suit, the action should be dismissed.

This case concerns a biological medication called trastuzumab. Defendants here—Celltrion Inc. ("Celltrion"), Celltrion Healthcare Co. Ltd. ("Celltrion Healthcare"), Teva Pharmaceuticals USA Inc. ("Teva USA"), and Teva Pharmaceuticals International GmbH ("TPIG")—are currently seeking approval under the Biologics Price Competition and Innovation Act of 2009 ("BPCIA" or "Act") to market "biosimilar" versions of both trastuzumab and another medication, rituximab. As part of the Act's information-exchange process—known as the "patent dance"—Plaintiffs Genentech Inc. ("Genentech"), Hoffmann-La Roche Inc. ("Roche"), and City of Hope ("Hope") asserted that Defendants' anticipated commercial launch of these products will infringe dozens of Plaintiffs' patents. In response, Defendants brought suit against Plaintiffs in the Northern District of California concerning both medications, seeking declarations that they will not infringe the asserted patents, and that those patents are, in any event, invalid or unenforceable. Defendants have pursued these declarations to obtain the legal certainty necessary to bring their products to market notwithstanding Plaintiffs' vague and unfounded infringement claims.

Plaintiffs have no plausible objection to litigating these questions in the Northern District of California—where Genentech is headquartered, and where all of the parties have engaged in activities related to the patents-in-suit. But rather than proceed with Defendants' first-filed litigation, Plaintiffs have instead filed two competing lawsuits in other districts—including this one—asserting claims for patent infringement against Defendants. This suit seeks to litigate the same set of trastuzumab patents as those at issue in the California litigation. The other suit, in the District of New Jersey, seeks to litigate the same set of rituximab patents as those at issue in

California. Together, these two actions present a virtual mirror image of Defendants' California litigation, which they initiated first. For several independent reasons, the Court should dismiss this Complaint rather than entertain a duplicative action.

First, under traditional rules of federal comity, courts should generally dismiss, stay, or transfer a later-filed action if it raises the same claims as a preexisting suit. *See, e.g.*, *Elecs. for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1347 (Fed. Cir. 2005). That principle squarely applies here: Plaintiffs' suit involves the same issues and the same parties as Defendants' earlier-filed suit in the Northern District of California. And no exception to this well-recognized "first-to-file" rule applies to this case. To the contrary, considerations of judicial economy and convenience to the parties strongly support allowing the litigation to proceed in the Northern District of California—where Genentech is headquartered, and where Defendants' parallel rituximab action (which involves many of the same patents) is pending before the same judge.

Second, the Court should dismiss Plaintiffs' action for failure to state a claim. Plaintiffs' Complaint simply recites the elements of patent infringement without providing any factual details about the relevant patent claims or reasons why Celltrion's proposed product or manufacturing processes supposedly infringe those claims. Indeed, Plaintiffs recognized during the patent dance that they had *no* basis to assert infringement as to *20* of the patents asserted here. The Complaint's conclusory allegations of infringement are insufficient to state a plausible claim for relief under *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007).

Finally, the Court should dismiss Plaintiffs' claims against two foreign Defendants—Celltrion Healthcare and TPIG—for lack of personal jurisdiction. Plaintiffs have failed to allege any relevant connection between these entities, Plaintiffs' causes of action, and this district.

NATURE AND STAGE OF THE PROCEEDINGS

Plaintiffs filed this action for patent infringement on January 12, 2018—one day *after*

Defendants filed a declaratory judgment action in the Northern District of California as to 38 of the patents-in-suit here. Defendants now bring this motion to dismiss or stay Plaintiffs' suit.

STATEMENT OF FACTS

Defendants are leading global pharmaceutical companies and pioneers in the development of biological medications. First Am. Compl., D.I. 40, ¶¶ 25, 27, in *Celltrion, Inc., et al. v. Genentech, Inc., et al.*, No. 4:18-cv-274 (N.D. Cal., Feb. 8, 2018) (attached hereto as Ex. A to Decl. of Kevin J. DeJong) (hereinafter, "Cal. FAC").[1] This litigation arises out of Defendants' efforts to develop and market a biological drug under the brand name Herzuma. Compl., D.I. 1, ¶ 9; Cal. FAC ¶¶ 26-27. Defendants seek FDA approval for Herzuma as a proposed "biosimilar" to Genentech's drug Herceptin, which FDA approved 20 years ago. Compl. ¶¶ 5, 36. Herceptin and Herzuma both contain trastuzumab, an antibody used to treat certain forms of cancer. *Id.* ¶¶ 3, 36. In an effort to bring competition to the market for this life-saving product, Celltrion has devoted significant time and resources over the past several years to developing and testing Herzuma, and Celltrion, Celltrion Healthcare, and TPIG have entered into an agreement to commercialize the product in the United States, where Teva USA will market the product. Cal. FAC ¶¶ 26-27.

Because Herzuma is a proposed biosimilar of Herceptin, the BPCIA allows Celltrion to follow an abbreviated pathway to FDA licensure that relies in part on the fact that FDA has already approved Herceptin (the "reference product"). *See* 42 U.S.C. §§ 262(i)(4), (k). In accordance with this statutory scheme, Celltrion submitted an "abbreviated biologic license application" ("aBLA") to FDA on May 30, 2017, and the agency notified Celltrion that it had

[1] In ruling on a motion to dismiss, the Court may rely on official records in a parallel action. *See Sands v. McCormick*, 502 F.3d 263, 268 (3d Cir. 2007); *cf. Wells Fargo Bank, N.A. v. Carnell*, No. 3:16-cv-130, 2017 WL 1498087, at *3 (W.D. Pa. Apr. 25, 2017) (articulating this principle in the context of abstention, and collecting decisions).

accepted the application on July 28, 2017. Cal. FAC ¶ 37. Consistent with the BPCIA's disclosure provisions, Celltrion sent Genentech (the "reference product sponsor") a copy of its aBLA and information regarding the manufacturing process for Herzuma within 20 days of FDA's acceptance of the aBLA. *See* 42 U.S.C. §§ 262(*l*)(1)(A), (*l*)(2); Cal. FAC ¶ 39. Celltrion furnished more than 280,000 pages of technical details and batch records describing Herzuma and its method of manufacture, including (i) the source, history, and generation of the cell substrate; (ii) the cell culture and harvest process; (iii) each and every purification process step; and (iv) raw materials used during the manufacture of Herzuma. Cal. FAC ¶ 39.

The parties then exchanged further information in several stages according to the provisions of the BPCIA—a process known as the "patent dance." On October 10, 2017, Genentech provided Celltrion with its "(3)(A) List," a document identifying the patents for which it "believe[d] a claim of patent infringement could reasonably be asserted" against Celltrion for marketing Herzuma. 42 U.S.C. § 262(*l*)(3)(A)(i); *see* Compl. ¶ 32. The list comprised the same 40 patents that Plaintiffs are now asserting in this action. Compl. ¶¶ 40-42; Cal. FAC ¶ 41. Celltrion timely responded on November 7, 2017, by providing its "(3)(B) Statement." *See* 42 U.S.C. § 262(*l*)(3)(B)(ii); Cal. FAC ¶ 42. With respect to 38 of the patents on the (3)(A) List, Celltrion offered a detailed explanation as to why the marketing of Herzuma would not result in infringement, or why the patents were otherwise invalid or unenforceable. *See* 42 U.S.C. § 262(*l*)(3)(B)(ii)(I); Cal. FAC ¶¶ 42, 45. [redacted] Genentech replied on January 5, 2018, with its "(3)(C) Statement." *See* 42 U.S.C. § 262(*l*)(3)(C) (requiring the reference product sponsor to transmit a statement describing "the factual and legal basis" for its opinion that its

patents would be "infringed by the commercial marketing of the [biosimilar]"); Compl. ¶ 34. Notably, Genentech failed to provide any arguments as to the infringement or validity of 20 patents on the (3)(A) List. *See* Compl. ¶ 34; Cal. FAC ¶¶ 46-47. Crucially, however, Genentech did not drop those 20 remaining patents, but instead purported to reserve the right to assert infringement claims as to those patents if it later decided, based on additional discovery, that Celltrion's (3)(B) Statement had been incomplete or misleading. Cal. FAC ¶ 47. [redacted] Celltrion wrote to Genentech indicating that, under Section 262(*l*)(4)(A), it wished to litigate all of the patents on Genentech's (3)(A) List. Compl. ¶ 35; Cal. FAC ¶ 49. Celltrion further notified Genentech, pursuant to Section 262(*l*)(8)(A), that commercial marketing of Herzuma would begin as early as 180 days from the date of the notice. Cal. FAC ¶ 50.

Under the BPCIA, providing a notice of commercial marketing triggers a new stage in the patent dance, allowing either side to bring a declaratory action to adjudicate any patent disputes that still exist between the parties at the time of the notice. *See* 42 U.S.C. § 262(*l*)(9)(A); *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1672 (2017). In light of the uncertainty created by Genentech's reservation of rights in its (3)(C) Statement, [redacted] Defendants [redacted] filed suit in the Northern District of California, seeking a declaration of noninfringement, invalidity, or unenforceability with respect to the 38 patents that Celltrion identified in its (3)(B) Statement. In addition to Genentech, the suit named Roche and Hope as defendants, in light of their ownership of several of the patents-in-suit. The Northern District of California was the natural forum for this litigation: both Genentech and Hope are based in California, and Genentech is headquartered in that district. Compl. ¶¶ 10, 12; Cal. FAC ¶¶ 19-21. Roche also has an office in the Northern District of California (which it shares with Genentech) that serves as its base for U.S.

commercial operations. Cal. FAC ¶ 22. By contrast, none of the Plaintiffs has its principal place of business in Delaware, and only Genentech is incorporated here. Compl. ¶ 10.

At the same time that they filed the trastuzumab action, the Defendants here also filed an action in the Northern District of California arising out of their plans to market another product, a proposed biosimilar containing the antibody rituximab. *See* Compl., D.I. 1, in *Celltrion, Inc., et al. v. Genentech, Inc., et al.*, No. 4:18-cv-276-JSW (N.D. Cal. Jan. 11, 2018). Like the trastuzumab action, the rituximab suit named Genentech, Roche, and Hope as defendants, and sought a declaration of noninfringement or invalidity as to numerous patents held by those entities. Substantial overlap exists between the two Northern District of California suits. Indeed, there are more patents in common between the two suits than are distinct: of the 38 patents at issue in the trastuzumab action and the 37 patents at issue in the rituximab suit, 24 patents are at issue in both. Unsurprisingly, these actions have been deemed related and have been assigned to the same judge. *See* Order, D.I. 63, in *Celltrion*, No. 4:18-cv-274 (N.D. Cal. Mar. 16, 2018).

Plaintiffs have no reasonable objection to resolving the parties' patent disputes in the Northern District of California, *where Genentech is headquartered*. Nevertheless, rather than proceed with those actions, Plaintiffs filed their own competing suits in the District of New Jersey and the District of Delaware on January 12, 2018. Their New Jersey suit is a mirror image of Defendants' rituximab action in the Northern District of California. *See* Compl., D.I. 1, in *Genentech, Inc., et al. v. Celltrion, Inc., et al.*, No. 1:18-cv-574 (D.N.J. Jan. 12, 2018). And their Delaware suit—the present case—is a mirror image of Defendants' trastuzumab suit. In other words, this action asserts causes of action for infringement involving the same 38 patents at issue in the California trastuzumab action.

SUMMARY OF ARGUMENT

I. The Court should dismiss this action because it duplicates Defendants' first-filed

action in the Northern District of California, and no exception to the first-to-file rule applies.

A. Under the "first-to-file" rule, federal courts generally dismiss, stay, or transfer a later-filed action if it raises the same claims as a preexisting suit. *See, e.g.*, *Electronics for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1347 (Fed. Cir. 2005). That rule applies with full force here, as Plaintiffs have asked this Court to resolve the *same* questions about the *same* patents involving the *same* parties as in Defendants' first-filed suit.

B. Plaintiffs fail to establish any "exceptional circumstances" to justify departing from the first-to-file rule. *Nexans Inc. v. Belden Inc.*, 966 F. Supp. 2d 396, 403-04 (D. Del. 2013). Defendants' California suit was not improperly "anticipatory," because Defendants had no "specific, concrete indications" that a suit by Plaintiffs was "imminent" at the time they filed their Complaint. *Genentech, Inc. v. Amgen, Inc.*, No. 17-cv-1407, 2018 WL 503253, at *6 (D. Del. 2018). Indeed, Genentech did not even provide infringement contentions as to 20 of the patents it originally asserted in its (3)(A) List, and yet it continued to hold over Celltrion's head the threat of an infringement suit at some undetermined point in the future. Whether Plaintiffs would assert 18 patents, 38 patents, or some other number—and when they would choose to do so—was uncertain, and Celltrion needed to seek declaratory relief to resolve that uncertainty. Moreover, there are no "other compelling factors" that justify departure from the first-to-file rule, which Plaintiffs must establish *even if* the California action could be characterized as anticipatory. *Elecs. for Imaging*, 394 F.3d at 1348. To the contrary, in the Northern District of California, a single judge can resolve all of the patent disputes between the parties that involve Celltrion's two proposed products in a manner that ensures efficiency and consistency. And that district is a convenient forum for all parties, particularly because Genentech and Hope are California-based organizations, and Genentech has its headquarters in that district.

II. The Court should also dismiss the Complaint for failure to plausibly plead any claims of patent infringement. Each of the Complaint's 40 counts simply includes a conclusory assertion that Celltrion committed a technical act of infringement by filing its aBLA, and that the trastuzumab product will infringe a particular patent. Plaintiffs allege no facts to support such an inference, and as a result their claims do not satisfy *Twombly*'s pleading standard. Plaintiffs' claims are particularly suspect given that, during the patent exchange, they could not identify *any* basis for alleging infringement as to 20 of the patents-in-suit here. Moreover, the infringement claims [redacted]

III. Finally, the Court should dismiss the claims against Defendants Celltrion Healthcare and TPIG for lack of personal jurisdiction. Those entities are not subject to general personal jurisdiction in Delaware, because they are neither incorporated nor headquartered in this state. And they are not subject to specific jurisdiction in Delaware, because Plaintiffs have alleged nothing more than that they will help place allegedly infringing products into the stream of commerce, which fails to establish purposeful availment of the forum. *See, e.g.*, *DNA Genotek Inc. v. Spectrum DNA*, 159 F. Supp. 3d 477 (D. Del. 2016).

ARGUMENT

I. THE COURT SHOULD DISMISS UNDER THE FIRST-TO-FILE RULE.

When two actions raising the same claims are filed in different jurisdictions, district courts routinely accord the first case priority over the later, duplicative suit. *See Elecs. for Imaging*, 394 F.3d at 1347.[2] This "first-to-file" rule plays an important role in promoting judicial

[2] The first-to-file rule in patent cases is governed by Federal Circuit precedent. *See Elecs. for Imaging*, 394 F.3d at 1345-46. Third Circuit precedent is also relevant, because "the basic underlying purpose of the rule is the same in both jurisdictions. *Fuisz Pharma LLC v. Theranos, Inc.*, No. 11-cv-1061, 2012 WL 1820642, at *3 n. 5. (D. Del. May 18, 2012).

economy and avoiding inconsistent judgments. *Futurewei Techs., Inc. v. Acacia Research Corp.*, 737 F.3d 704, 708 (Fed. Cir. 2013). A party that brings a duplicative action must present "exceptional circumstances" to allow its later-filed suit to proceed. *Nexans*, 966 F. Supp. 2d at 403-04 (quotation marks omitted). These considerations, moreover, "do not change simply because the first-filed action is a declaratory action." *Elecs. for Imaging*, 394 F.3d at 1348 (quotation marks omitted). Rather, the rule applies with full force to suits seeking declaratory relief, "giv[ing] precedence to a first-filed declaratory judgment action over a later-filed infringement action when the declaratory action can resolve the various legal relations in dispute and afford relief from the controversy that gave rise to the proceeding." *Nexans*, 966 F. Supp. 2d at 403 (quotation marks omitted).

These principles apply in full to the present dispute, requiring the dismissal (or at least a stay) of Plaintiffs' duplicative lawsuit. Plaintiffs' action involves the same parties and the same subject matter as Defendants' first-filed action in the Northern District of California. And no exception to the first-to-file rule is applicable. In particular, Defendants' declaratory judgment action cannot be characterized as "anticipatory"; at the time Celltrion provided Genentech with its notice of commercial marketing, Genentech's actions had left Celltrion with no concrete indication of whether Plaintiffs would assert 18 patents, 38 patents, or some other number—much less whether they would do so immediately. And even if this action *could* be deemed anticipatory, the first-to-file rule would still control, because allowing the litigation to proceed in the Northern District of California would promote the efficient use of both the courts' and the parties' resources. Accordingly, the Court should dismiss or stay Plaintiffs' suit.[3]

[3] The first-filed California action has proceeded further than this case: a motion to dismiss (which implicates the first-to-file issue) is fully briefed and scheduled for argument on April 27. This Court can defer ruling on this motion until the Northern District of California has ruled.

A. This Case Involves The Same Patents And The Same Parties As The Previously Filed California Action.

The first-to-file rule applies whenever successive lawsuits "involve[e] the same parties and the same issues." *Nexans*, 966 F. Supp. 2d at 403 (quotation marks omitted). There can be no serious question that this condition is met here. In their first-filed action, Defendants requested a declaration that, upon commercial launch, their trastuzumab product will not infringe 38 patents of the patents designated in Genentech's (3)(A) Statement, and that those 38 patents are invalid or unenforceable. Cal. FAC ¶¶ 89-483. In this responsive action, Plaintiffs now allege infringement with respect to *the same* 38 patents. The first-to-file rule plainly applies to such "mirror-image litigation." *Nexans*, 966 F. Supp. 2d at 403.

Indeed, the posture of this case is materially indistinguishable from the posture in *Nexans*. There, as here, a company filed an action seeking a declaration of noninfringement and invalidity with respect to several patents. *See id.* at 400. Like Celltrion, the company faced a potential threat of infringement litigation—one communicated by the patent owner in a warning letter after the expiration of a standstill agreement. *See id.* Rather than proceeding with the declaratory action, the defendants in that first-filed suit—like Genentech here—immediately brought a mirror-image complaint alleging infringement of the same patents in another judicial district. *See id.* Recognizing that the duplicative action clearly violated the first-to-file rule, the court refused to dismiss the declaratory action and issued an injunction to bar the subsequent infringement action. *Id.* at 406. The same result is appropriate here.

Plaintiffs may try to argue that the current action is not duplicative because they have asserted claims for infringement of all 40 patents on their (3)(A) List in this litigation, rather than the 38 patents that Defendants have identified in their California Complaint. But controlling precedent "gives little weight" to whether "the second-filed infringement action is broader than

the first filed declaratory judgment action." *Micron Tech., Inc. v. Mosaid Techs., Inc.*, 518 F.3d 897, 903 (Fed. Cir. 2008); *see also Amgen*, 2018 WL 503253, at *6 (concluding that the presence of a "few additional patents" in one action was not significant in deciding whether to order transfer). As the Federal Circuit has explained, this rule is necessary to prevent gamesmanship, because patent owners could otherwise "file an artificially broader infringement suit to avoid declaratory judgment jurisdiction." *Micron*, 518 F.3d at 903. That is exactly what Plaintiffs seek to do here. [redacted]

B. This Action Does Not Fall Within Any Exceptions To The First-Filed Rule.

As explained, pp. 8-9, *supra*, precedent "favors the first-to-file rule in the absence of circumstances making it 'unjust or inefficient' to permit a first-filed action to proceed to judgment." *Elecs. for Imaging*, 394 F.3d at 1348. Here, Defendants can show no evidence of injustice or inefficiency in moving forward with the California litigation.[4]

1. The California action was not "anticipatory."

In deciding whether to depart from the first-to-file rule, courts may consider as "one

[4] In the Northern District of California action, Plaintiffs have moved to dismiss on the ground that Defendants' claims for declaratory relief are supposedly barred by the BPCIA. As Defendants' have explained at length in their opposition there, the BPCIA imposes no bar to their action because Celltrion fully complied with its obligations in the patent dance and its provision of a notice of commercial marketing allowed either side to seek immediate declaratory relief. *See* 42 U.S.C. § 262(*l*)(9)(A); p. 5, *supra*. But there is no need for this Court to consider this question, which is fully briefed in the first-filed action and should be decided there.

factor in the analysis" whether a plaintiff's first-filed suit was "anticipatory." *Elecs. for Imaging*, 394 F.3d at 1348. But courts will not label an action "anticipatory" merely because the first-filing party knew that an opposing lawsuit was likely at some point in the future. Rather, for an action to qualify as "anticipatory"—and to potentially displace the first-to-file rule—a defendant must demonstrate that "the plaintiff in the first-filed action filed suit on receipt of *specific, concrete indications* that a suit by the defendant was *imminent*." *Amgen*, 2018 WL 503253, at *6 (emphasis added) (quotation marks omitted). Here, there were no such indications of an imminent suit on all of the patents at issue before Defendants filed their California Complaint.

In response, Plaintiffs will likely invoke this Court's decision in *Amgen*, in which Genentech and Hope successfully argued that a declaratory action filed by a biosimilar applicant was anticipatory. But the facts that drove that decision support the opposite result here. As this Court explained, by the time Amgen filed its declaratory action against Genentech and Hope, "it had already been sued" by those same parties in the District of Delaware over a dispute involving the *same biosimilar product* with regard to the BPCIA's information exchange. *Id.* at *7. This Court had dismissed that earlier action as premature and explained that Plaintiffs should file a new action challenging Amgen's compliance with the BPCIA as soon as an action for "immediate patent infringement" became ripe. *Id.* Given this litigation history, this Court held that Amgen's suit in California for declaratory relief was anticipatory. *Id.*

Here, by contrast, there were no "specific, concrete indications" that Defendants were facing an "imminent" suit at the time they filed their California Complaint. Before this action, Plaintiffs had not filed suit in this district (or anywhere else) against Celltrion over any issues arising from its trastuzumab aBLA. To the contrary, Genentech did not even provide infringement contentions as to 20 of the patents it asserted in its (3)(A) List, all while continuing

to hold over Celltrion's head the threat of an infringement suit at some point in the future with respect to those patents. These actions—which obscured when, if ever, Plaintiffs would file an infringement suit with respect to some of the patents in issue—cast an unacceptable legal cloud over Defendants' proposed product launch and created an immediate need for declaratory relief. Moreover, there is there no basis to accuse Defendants of filing an anticipatory suit in order to forum shop, because they filed declaratory actions in the state in which Genentech and Hope *are headquartered*, and in which Roche's principal place of business for its U.S. commercial operations is located. *See* pp. 5-6, *supra*. One would be hard-pressed to find a more logical forum for this dispute than the Northern District of California.

Because there has been no prior litigation in this district between the parties involving the trastuzumab product or the patents-in-suit, the only basis for Plaintiffs to contend that the California suit was anticipatory is that the parties were engaged in the BPCIA's patent dance, through which Genentech provided its (3)(A) List and identified a subset of patents that the parties should litigate. But the mere fact that parties have engaged in negotiations or discussions over the scope of a patent owner's rights—even negotiations or discussions that might lead to litigation—does not make a suit "anticipatory." *See Nexans*, 966 F. Supp. 2d at 404 (declining to find a suit "anticipatory" even though the parties were engaged in settlement negotiations and had entered into a standstill agreement that was in place until shortly before the action was filed).

Nor does the structure of the BPCIA support an argument that a declaratory action by the applicant before the reference product sponsor files an infringement suit is inherently anticipatory. To begin with, the Act recognizes several ways that applicants and reference product sponsors may resolve patent disputes without litigation. For example, the information exchange might convince the reference product sponsor that it should license the patents at issue.

See 42 U.S.C. § 262(*l*)(3)(A)(ii). Or the exchange might convince the reference product sponsor to abandon its infringement claims altogether. Moreover, the BPCIA clearly contemplates that aBLA applicants have an equal right to initiate patent litigation following an information exchange and the applicant's notice of commercial marketing. Under Section 262(*l*)(9)(A), if the applicant provides its aBLA and information about its manufacturing process to the reference product sponsor, then *neither* party may bring a declaratory judgment action concerning the designated patents *until* the applicant gives notice of commercial marketing. But once that notice is provided, *either* party may pursue declaratory relief. *See* 42 U.S.C. § 262(*l*)(9)(A); *Sandoz*, 137 S. Ct. at 1672. This equal right to initiate litigation serves the BPCIA's objectives of facilitating prompt resolution of patent disputes to promote competition: unless and until it faces a competing suit for a declaratory judgment initiated by the applicant, a reference product sponsor has significant incentives to stretch out the "patent dance" for as long as possible in order to stay alone on the market (and earn millions of additional dollars every day).[5]

Ultimately, the argument that Defendants' California suit was "anticipatory" proves far too much, because it would render virtually *every* declaratory judgment action "anticipatory"—and certainly every declaratory judgment action initiated by a biosimilar applicant. After all, to obtain a declaratory judgment, a plaintiff must show that there is an "actual controversy" between the parties of "sufficient immediacy and reality." *MedImmune, Inc. v. Genentech, Inc.*,

[5] There are at least two ways a sponsor could drag out the patent dance. First, the sponsor could refuse to engage in good faith negotiations with the biosimilar applicant under paragraph (4). There is no requirement in the statute as to when the good faith negotiations must begin; the statute provides only that they are to take place "[a]fter" the sponsor provides its (3)(C) Statement. 42 U.S.C. § 262(*l*)(4)(A). Second, the sponsor could refuse to engage in the patent resolution process of paragraph (5)(B). Although this process does have a timing requirement—the sponsor shall provide a list of patents for immediate litigation within five days of the applicant's notifying the sponsor of the number of patents it will list, *see id.* § 262(*l*)(5)(B)(i)—the statute does not provide a specific consequence if a sponsor fails to comply.

549 U.S. 118, 126-27 (2007) (quotation marks omitted). Plaintiffs' approach would mean that if a declaratory action is sufficiently concrete to establish subject-matter jurisdiction (because a coercive suit had been threatened), it could then be dismissed as per se anticipatory. But that is not the law: as noted, p. 9, *supra*, the Federal Circuit has made clear that the first-to-file rule fully applies to declaratory judgment actions. *Elecs. for Imaging*, 394 F.3d at 1348.

In short, neither the parties' participation in the patent dance, nor any other actions taken by Genentech, Roche, or Hope prior to the filing of the California actions, gave Defendants "specific, concrete indications" that a suit by Plaintiffs was "imminent." *Amgen*, 2018 WL 503253, at *6. Defendants' California suit was not anticipatory, and the ordinary first-to-file rule should apply.

2. Considerations of convenience and judicial economy further support dismissal.

The Federal Circuit has held that even "[a]n anticipatory lawsuit does not lose its priority under the first-to-file rule, unless there are *additional* convenience factors that do not favor a transfer." *Amgen*, 2018 WL 503253, at *7 (emphasis added). Courts thus must ask whether "considerations of judicial and litigant economy[] and the just and effective disposition of disputes" favor allowing the later-filed suit to proceed. *Elecs. for Imaging*, 394 F.3d at 1347 (quotation marks omitted). Here, such considerations *bolster* the case for letting the first-filed California action go forward, while dismissing or staying this follow-on suit.

First, the Northern District of California is a more convenient and logical forum than Delaware because Genentech is based there. Indeed, all of the Plaintiffs have substantial ties with California: Genentech is headquartered in the Northern District, Roche bases its U.S. commercial operations out of Genentech's South San Francisco headquarters, and Hope is a California non-profit organization. Compl. ¶¶ 10, 12.; Cal. FAC ¶¶ 17-22. Moreover, upon

information and belief, Plaintiffs collaborated at Genentech's South San Francisco headquarters on the development of the subject-matter of the patents-in-suit. Cal. FAC ¶ 23. By contrast, none of the parties has its principal place of business in Delaware, and there has been no act of infringement in the state. To be sure, one party on each side—Genentech and Teva USA—is incorporated in Delaware. But that fact does not show that Delaware will be a more convenient or appropriate forum than the Northern District of California. *Cf. Amgen*, 2018 WL 503253, at *3 (declining to transfer action where the *sole* defendant, which had also filed the aBLA, was incorporated in Delaware in addition to one of the two plaintiffs).

Second, the Northern District of California is a preferable forum because a single judge (Judge White) will preside over the entire controversy between the parties with respect to the patents-in-suit. As discussed, p. 6, *supra*, the parties in this action are simultaneously engaged in parallel patent litigation involving another biosimilar product (rituximab). The overlap between the cases is considerable, with 24 of the same patents at issue in both actions. *Compare* Cal. FAC, *with* First Am. Compl., D.I. 38, in *Celltrion*, No. 4:18-cv-276-JSW (N.D. Cal. Feb. 8, 2018). As this Court recognized in *Amgen*, "efficiencies can be gained when all related cases are litigated together." 2018 WL 503253, at *5. Judge White is in a position to realize these efficiencies through his management of the parallel trastuzumab and rituximab actions: addressing both of these matters together will allow him to coordinate discovery and ensure a speedy, consistent resolution of the many questions common to both cases, including questions of claim construction, invalidity, and noninfringement.

By contrast, Plaintiffs' proposal splits these overlapping patent cases between the District of Delaware (for the trastuzumab litigation) and the District of New Jersey (for the rituximab litigation). This would inevitably lead to the sort of "wastefulness of time, energy and money"

that results from letting two cases involving "the same issues" and the same parties proceed in different district courts. *Cont'l Grain Co. v. The Barge FBL-585*, 364 U.S. 19, 26 (1960). The burden imposed by parallel actions would be particularly acute here, because the Celltrion entities that developed the biosimilar products are Korean companies. Celltrion personnel would have to travel over 6,000 miles to participate in separate, uncoordinated proceedings in two different judicial districts on the East Coast. Coordinated proceedings before a single judge in California would mitigate this inconvenience and avoid resulting scheduling delays.

Plaintiffs have attempted to justify filing their suit in this district by pointing to ongoing actions against *different* parties (Amgen and Pfizer). But the three Amgen and Pfizer suits are a patchwork of competing claims and patents: only 12 of the 40 patents at issue in this case are also at issue in all three of the other cases. Moreover, those suits involve different companies using different processes to produce their biosimilar products—and two of the three suits involve a different biosimilar product altogether (bevacizumab). A dispute over whether Amgen's or Pfizer's manufacturing techniques for bevacizumab infringe particular patents will not decide whether Defendants' processes for manufacturing trastuzumab also infringe those patents. Even Genentech agrees: in a recent letter, Genentech proposed that the suits before this Court involving different biosimilar products *should be decoupled* because although they "involve certain overlapping . . . patents, they are really very different." D.I. 77, at 2, in *Genentech, Inc., et al. v. Amgen, Inc.*, C.A. No. 17-1471-GMS (D. Del. Mar. 16, 2018). Genentech's decision to bring different cases concerning different products in different jurisdictions undermines any claim that it seeks an "efficient" resolution of these issues before a single court.

In the end, Federal Circuit case law requires Plaintiffs to show not that there are some plausible reasons for litigating here, but instead that litigation in California is affirmatively unjust

or inefficient. *See Elecs. for Imaging*, 394 F.3d at 1347. Plaintiffs cannot carry that burden and, accordingly, cannot displace the first-to-file rule.

II. THE COMPLAINT FAILS TO STATE A CLAIM BECAUSE IT RELIES ON CONCLUSORY ASSERTIONS OF PATENT INFRINGEMENT.

It is firmly established that all claims for patent infringement "are now subject to the pleading standards established by *Twombly* and *Iqbal*," which "requir[e] plaintiffs to demonstrate a plausible claim for relief." *Prowire LLC v. Apple, Inc.*, No. 17-cv-223, 2017 WL 3444689, at *2 (D. Del. Aug. 9, 2017) (quotation marks omitted) (collecting decisions). To satisfy this plausibility standard, the plaintiff must do more than identify patents it owns and assert the "legal conclusion" that the defendant's product will infringe unspecified patent claims. *SIPCO, LLC v. Streetline, Inc.*, 230 F. Supp. 3d 351, 353 (D. Del. 2017). As the Supreme Court has explained, "threadbare recitals of a cause of action's elements, supported by mere conclusory statements," do not state a plausible claim to relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

But that is all that Plaintiffs' Complaint provides. Its 40 counts of patent infringement all follow the same formula: alleging (1) that Genentech included the relevant patent in its (3)(A) List to Celltrion, (2) that Genentech "reasonably believes," based on unspecified public information and/or information provided by Celltrion, that Celltrion's submission of its aBLA for the trastuzumab product is a technical act of infringement as to the patent at issue "either literally or under the doctrine of equivalents," and (3) that Plaintiffs collectively "reasonably believe," based on unspecified information from the same sources, that Defendants' "activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use" of its trastuzumab product will infringe the applicable patent "in violation of 35 U.S.C. § 271(a), (b), and/or (g)." Compl. ¶¶ 93-384. Such threadbare recitals and conclusory statements provide no basis—let alone a *plausible* basis—to infer that Plaintiffs are entitled to relief.

The Complaint also alleges that Genentech has, pursuant to the BPCIA process, "provided detailed, claim-by-claim infringement contentions to Celltrion" as to *some* of the asserted patents. *E.g.*, Compl. ¶ 95. But the Complaint does not actually put forward any of the substance from those contentions and cannot incorporate them by reference to state a claim under *Twombly*. Moreover, the Complaint conspicuously omits even this conclusory allegation from 20 of its counts, because Genentech did not provide any infringement contentions to Celltrion with respect to 20 of the patents here. *See* p. 5, *supra*. Genentech has thus provided no basis to bring claims for infringement of these patents. In addition, the Complaint includes [redacted]

III. THE COURT LACKS PERSONAL JURISDICTION OVER DEFENDANTS CELLTRION HEALTHCARE AND TPIG.

Plaintiffs have the burden of establishing personal jurisdiction over each defendant. *See Avocent Huntsville Corp. v. Aten Int'l Co., Ltd.*, 552 F.3d 1324, 1330 (Fed. Cir. 2008).[6] General personal jurisdiction exists only where a defendant's "affiliations with the [forum] State are so continuous and systematic as to render [it] essentially at home" there. *BNSF Ry. Co. v. Tyrrell*, 137 S. Ct. 1549, 1558 (2017) (quotation marks omitted). And specific jurisdiction exists only

[6] Federal Circuit case law applies to questions of personal jurisdiction in patent infringement suits. *See Avocent*, 552 F.3d at 1329.

where "the defendant has purposefully directed [its] activities at residents of the forum, and the litigation results from alleged injuries that arise out of or relate to those activities." *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985) (citations and quotation marks omitted).

Here, Plaintiffs cannot establish either type of jurisdiction over Defendants Celltrion Healthcare and TPIG. These entities are plainly not subject to general jurisdiction in Delaware: they are neither incorporated nor headquartered anywhere in the United States (let alone in Delaware specifically). Nor have Plaintiffs alleged a sufficient basis to establish specific jurisdiction. Neither company submitted the aBLA at issue in this case; thus, although Plaintiffs appear to rely on that filing as a basis for personal jurisdiction over all of the Defendants, Compl. ¶ 27, that alleged basis does not apply to Celltrion Healthcare and TPIG. Plaintiffs also allege that these two entities will play an unspecified role in distributing Herzuma "in the United States." Compl. ¶ 29. But courts have consistently held that the mere placement of goods into the nationwide stream of commerce, without more, is insufficient to establish personal jurisdiction: "what is necessary is a deliberate targeting of the forum." *See Shuker v. Smith & Nephew PLC*, 885 F.3d 760, 780 (3d Cir. 2018) (quotation marks omitted). Plaintiffs have shown no such targeting here. Indeed, this case is on all fours with the Court's decision in *DNA Genotek Inc. v. Spectrum DNA*, 159 F. Supp. 3d 477 (D. Del. 2016). There, the Court explained that the sole fact that a foreign corporation has "deliver[ed] [an] accused product" to a third party "who, in turn, is responsible for placing the accused product into the stream of commerce" falls far short of the requirements for establishing personal jurisdiction. *Id.* at 482. Here, Plaintiffs can only allege that TPIG and Celltrion Healthcare will be involved in placing a product into the stream of commerce sometime in the future.

CONCLUSION

For the foregoing reasons, the Court should dismiss or stay this action.

Respectfully submitted,

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Dated: April 16, 2018

CERTIFICATION PURSUANT TO LOCAL RULE 7.1.1

Undersigned counsel for Defendants hereby certifies that reasonable efforts have been made to resolve the subject of this motion.

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CERTIFICATE OF SERVICE

I, Nathan R. Hoeschen, hereby certify that on April 16, 2018, this document was served on the persons listed below in the manner indicated:

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